

CLAIMS

1. A pharmaceutical agent comprising 1) an LHRH receptor agonist or antagonist or a salt thereof in combination with 2)
5 an androgen receptor agonist or a salt thereof.
2. The pharmaceutical agent of claim 1, wherein the LHRH receptor agonist is leuporelin.
- 10 3. The pharmaceutical agent of claim 1, wherein the androgen receptor agonist is a steroidal androgen receptor agonist.
4. The pharmaceutical agent of claim 3, wherein the steroidal androgen receptor agonist is one or more compounds selected
15 from the group consisting of dehydroepiandrosterone, testosterone, dihydrotestosterone, androstenedione, Mestanolone, Oxymesterone, Methandrostenolone, Fluoxymesterone, Chlorotestosterone acetate, Methenolone acetate, Oxymetholone, Stanazolol, Furazabol, Oxandrolone, 19-Nortestosterone,
20 Norethandrolone, Ethylestrenol and Norbolethone, or a salt thereof.
5. The pharmaceutical agent of claim 1, wherein the androgen receptor agonist is a non-steroidal androgen receptor agonist.
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6. The pharmaceutical agent of claim 1, which is an agent for the prophylaxis or treatment of a hormone-dependent disease.
7. The pharmaceutical agent of claim 6, wherein the hormone-
30 dependent disease is prostate cancer.
8. The pharmaceutical agent of claim 1, wherein the LHRH receptor agonist or antagonist or a salt thereof is used as a

sustained-release preparation or an embedded agent.

9. The pharmaceutical agent of claim 8, wherein the sustained-release preparation is a sustained-release microcapsule.

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10. The pharmaceutical agent of claim 9, wherein the sustained-release microcapsule is a long-term sustained-release microcapsule that releases an LHRH receptor agonist or antagonist or a salt thereof for not less than 2 months.

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11. An agent for the prophylaxis or treatment of bone metastatic prostate cancer, which comprises an androgen receptor agonist or a salt thereof.

15 12. The agent of claim 11, wherein the bone metastatic prostate cancer cell is highly sensitive to androgen.

13. The agent of claim 11, wherein the androgen receptor agonist is a steroidal androgen receptor agonist.

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14. The agent of claim 13, wherein the steroidal androgen receptor agonist is one or more compounds selected from the group consisting of dehydroepiandrosterone, testosterone, dihydrotestosterone, androstenedione, Mestanolone, Oxymesterone, Methandrostenolone, Fluoxymesterone, Chlorotestosterone acetate, Methenolone acetate, Oxymetholone, Stanazolol, Furazabol, Oxandrolone, 19-Nortestosterone, Norethandrolone, Ethylestrenol and Norbolethone, or a salt thereof.

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15. The agent of claim 11, wherein the androgen receptor agonist is a non-steroidal androgen receptor agonist.

16. An agent for the prophylaxis or treatment of prostate cancer, which comprises a non-steroidal androgen receptor agonist or a salt thereof.

5 17. The agent of claim 16, wherein the prostate cancer cell is highly sensitive to androgen.

18. A method for treating prostate cancer, which comprises administering an effective amount of an LHRH receptor agonist
10 or antagonist or a salt thereof to a mammal, and after prostate cancer cell has become highly sensitive to androgen, administering an effective amount of an androgen receptor agonist or a salt thereof.

15 19. A method for treating breast cancer or uterine cancer, which comprises administering an effective amount of an LHRH receptor agonist or antagonist or a salt thereof to a mammal, and after breast cancer or uterine cancer cell has become highly sensitive to estrogen, administering an effective
20 amount of an estrogen receptor agonist or a salt thereof.

20. A method for treating prostate cancer, which comprises administering an effective amount of an LHRH receptor agonist or antagonist or a salt thereof in combination with an
25 effective amount of an androgen receptor agonist or a salt thereof to a mammal.

21. A method for treating breast cancer or uterine cancer, which comprises administering an effective amount of an LHRH
30 receptor agonist or antagonist or a salt thereof in combination with an effective amount of an estrogen receptor agonist or a salt thereof to a mammal.

22. A method for treating prostate cancer, which comprises administering an effective amount of an LHRH receptor agonist or antagonist or a salt thereof in combination with an effective amount of an androgen receptor agonist or a salt thereof to a mammal to shrink a prostate tumor, and then performing a surgery or radiation treatment.

23. A method for treating breast cancer or uterine cancer, which comprises administering an effective amount of an LHRH receptor agonist or antagonist or a salt thereof in combination with an effective amount of an estrogen receptor agonist or a salt thereof to a mammal to shrink a breast tumor or uterine tumor, and then performing a surgery or radiation treatment.

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24. A method for treating prostate cancer, which comprises 1) administering an androgen receptor agonist or a salt thereof to a highly androgen sensitive prostate cancer cell for a certain time period, 2) thereafter when the androgen sensitivity of the cancer cell has become lower, administering an effective amount of 1 or 2 compounds selected from an LHRH receptor agonist or antagonist and an antiandrogen drug, or a salt thereof, or when the androgen sensitivity of the cancer cell has increased, administering an effective amount of an androgen receptor agonist or a salt thereof, and 3) repeating the step 2) as necessary until an object of cancer treatment is achieved.

25. The method of claim 24, which comprises alternately administering an effective amount of 1) an androgen receptor agonist or a salt thereof and 2) 1 or 2 compounds selected from an LHRH receptor agonist or antagonist and an antiandrogen drug, or a salt thereof.

26. The method of claim 25, comprising changing the administration drug after a lapse of 3 months to 5 years.

5 27. A method for treating breast cancer or uterine cancer, which comprises 1) administering an estrogen receptor agonist or a salt thereof to a highly estrogen sensitive breast cancer or uterine cancer cell for a certain time period, 2) thereafter when the estrogen sensitivity of the cancer cell
10 has become lower, administering an effective amount of 1 or 2 compounds selected from an LHRH receptor agonist or antagonist and an antiestrogen drug, or a salt thereof, or when the estrogen sensitivity of the cancer cell has increased, administering an effective amount of an estrogen receptor
15 agonist or a salt thereof, and 3) repeating the step 2) as necessary until an object of cancer treatment is achieved.

28. The method of claim 27, which comprises alternately administering an effective amount of 1) an estrogen receptor
20 agonist or a salt thereof and 2) 1 or 2 compounds selected from an LHRH receptor agonist or antagonist and an antiestrogen drug, or a salt thereof.

29. The method of claim 28, comprising changing the
25 administration drug after a lapse of 3 months to 5 years.

30. Use of an androgen receptor agonist or a salt thereof for the production of an agent for the prophylaxis or treatment of bone metastatic prostate cancer.

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31. Use of a non-steroidal androgen receptor agonist or a salt thereof for the prophylaxis or treatment of prostate cancer.

32. Use of an LHRH receptor agonist or antagonist or a salt thereof for the production of a pharmaceutical agent comprising 1) an LHRH receptor agonist or antagonist or a salt thereof in combination with 2) an androgen receptor agonist or
5 a salt thereof.

33. Use of an androgen receptor agonist or a salt thereof for the production of a pharmaceutical agent comprising 1) an LHRH receptor agonist or antagonist or a salt thereof in
10 combination with 2) an androgen receptor agonist or a salt thereof.